

Priority

The Examiner states that Applicants did not comply with 35 U.S.C. 119(e) and 120. Correction was requested. Applicants have amended the specification to comply with the Examiner's request. Applicants have clarified the language of the application's first paragraph; no new matter was added.

Drawings

The Examiner objects to the drawings, because figure 2 has not been identified as figure 2a and figure 2b. Applicants have attached formal drawing and have corrected figure 2 to read figure 2a and figure 2b. Support for this amendment is found in the specification on page 4, lines 24-26; no new matter was added. Applicants submit that this amendment obviates the Examiner's objection.

Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 15-18 and 30-34 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

Claims 15 and 32

The Examiner asserts that in claims 15 and 32 it is not clear how "at least one alignment means" structurally cooperates with the rest of the previously recited structures of the device.

Initially, Applicants note that claims 15 and 32 did not recite "at least one alignment means." Rather, the claims recited "at least one alignment feature." Moreover, claims 15 and 32 have been amended to include language that clarifies how at least one alignment feature structurally cooperates with the rest of the previously recited structures of the device. Namely, the

hybridization chamber includes at least one alignment feature, wherein the alignment feature facilitates alignment of said lid with said base plate. Accordingly, Applicants submit that claims 15 and 32 are in condition for allowance.

Claim 17

The Examiner states that claim 17 is not clear as to whether microtiter plate is being positively recited as part of the claimed device or that the base is merely capable of holding a microtiter plate. The Examiner recalls that claim 13 recites “a base cavity for holding a first array.”

In response, Applicants note that the microtiter plate is not necessarily positively claimed. That is, it is not a required element of claim 17. Rather, the claimed base plate is designed to hold a first array and in the case of claim 17, the base plate is designed to hold a microtiter plate.

Claims 18 and 34

The Examiner asserts that in claims 18 and 34, while the device includes “at least one fluid handling device” it is not clear how the “at least one handling device” structurally cooperates with the rest of the previously recited structures of the device.

Applicants have amended claims 18 and 34 to include language clarifying how the “at least one handling device” structurally cooperates with the rest of the previously recited structures of the device. Namely, the chamber is connected to the fluid handling device. As such Applicants respectfully request the Examiner to withdraw the rejection.

Claim 30

The Examiner states that “said first array” in claim 30 lacks antecedent basis. Applicants have amended the claims to provide proper antecedent basis. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection.

Claim 31

The Examiner states that "said second array" in claim 31 lacks antecedent basis.

Applicants have amended the claims to provide proper antecedent basis.

Accordingly, Applicants submit that in light of the above amendments and clarifications, the claims comply with 35 USC § 112, second paragraph. Applicants respectfully request the Examiner to withdraw the rejection.

Claim Rejections under 35 U.S.C. § 102

Claims 13, 14, 17, 29, 30, and 31 are rejected under 35 U.S.C. § 102 as being anticipated by Kolehmainen *et al.* The Examiner asserts that Kolehmainen discloses a device which is capable of being used for hybridization, which includes a base plate, a first array component, a lid with ports for immobilizing a second array of fiber optic bundles, and a sealant between the base plate and the lid. Applicants respectfully traverse.

The Kolehmainen *et al.* invention relates to automatic transportation, processing and measurement of chemiluminescence and bioluminescence in discrete samples contained in depressions on a light reflecting tape (5). Emitted light from samples in the depressions of the reflecting tape is conducted through bundles of optical fibers (36) to photomultiplier tubes (37). The ends of the fibers are isolated from outside light by O-rings (38), which are pressed against the tape that is supported by the grooved block (27).

In contrast claims 13, 14, 17, 29, 30, and 31 provide a hybridization chamber comprising a base plate wherein a base cavity for holding a first array component is formed in the base plate, a lid comprising at least one component port for immobilizing a second array component, and a sealant between the base plate and the lid. The first array component comprises more than one

discrete element, because the invention claims an array. The claims also provide that the second array component is a fiber optic bundle (claim 14) and the first array component is a microtiter plate (claim 17).

As the Examiner is aware, "[i]t is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986). The law is well established that in order to anticipate a claim, the prior art must disclose "each and every element" of the claimed invention. *SSIH Equipment S.A. v. U.S. Inc. Int'l. Trade Commission*, 218 USPQ 678, 688 (Fed. Cir. 1983). As stated by the Federal Circuit in *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990), "[f]or a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." See also *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 33 USPQ2d 1496 (Fed. Cir. 1995).

Here, the prior art reference does not anticipate the present invention, because not only does Kolehmainen *et al.* not disclose "each and every element" of the claimed invention, but also every element of the claimed invention is not identically shown in Kolehmainen *et al.* Kolehmainen *et al.* does not teach a base plate. Rather, Kolehmainen teaches a grooved block to which reflective tape is applied. The tape forms depressions on the block. Kolehmainen teaches a single sample in each depression. That is, each depression of Kolehmainen only conducts a single assay, whereas the cavity in the base plate in the present invention is for holding an array, which necessarily includes more than one element. That is, the depressions in the tape of Kolehmainen are for holding a single sample, while the cavity in the base plate as claimed (in claim 13) is for holding an array. Thus the base cavity of the claimed base plate is formed in the

base plate so as to hold first array component, while the "cavity" of Kolehamainen only holds a single sample.

Moreover, claim 29 recites that the chamber comprises a base plate with a base cavity, a first array component in the base cavity and a lid comprising a first component port wherein the component port comprises a second array component. That is, the chamber as recited in claim 29 includes both a first and a second array component. In contrast, the device as set forth in Kolehamainen does not include an array within the cavities (the depressions). That is, the depressions include only a single sample. Accordingly, applicants submit that Kolehamainen fails to teach each and every element of claim 29.

Because each and every element of the claims are not identically disclose in Kolehamainen, Applicants respectfully request that the rejection be withdrawn.

Claim Rejections under 35 U.S.C. § 103 Kolehmainen *et al.* in view of Hafeman *et al.*

The Examiner rejects claims 15, 16, 32, and 33 under 35 U.S.C. § 103 as being unpatentable over Kolehmainen *et al.* in view of Hafeman *et al.* Specifically, the Examiner states that although Kolehmainen *et al.* does not teach the use of alignment structures between the base and lid, Hafeman *et al.* discloses that it is know in the art to provide male/female alignment structures on a base and lid so as to ensure proper alignment between the lid holding the fiber optic bundles an the sample wells. Applicants respectfully traverse.

The Kolehmainen *et al.* reference has been discussed above.

Hafeman *et al.* discloses spectrophotometers used to measure the optical density of liquid samples placed in a cuvette with a unique cover that eliminates the problems with the meniscus

effect and the evaporation effect. Also disclosed is a multi-assay plate and lid that includes male and female alignment structures.

In contrast, claims 15, 16, 32, and 33 provide a hybridization chamber for holding a first array component, a lid comprising at least one component pair for immobilizing a second array component, a sealant and at least one alignment feature, wherein said at least one alignment feature facilitates alignment of said lid with said base plate (claim 15), and wherein said at least one alignment feature is a male and female fitting (claim 16).

When rejecting claims under 35 U.S.C. §103, the Examiner bears the burden of establishing a *prima facie* case of obviousness. See, e.g., *In re Bell* 26 USPQ2d 1529 (Fed. Cir. 1993); M.P.E.P. Section 2142. To establish a *prima facie* case, three basic criteria must be met: (1) the prior art, either alone or in combination, must teach or suggest every limitation of the rejected claims; (2) the prior art must provide one of ordinary skill with a suggestion or motivation to modify or combine the teachings of the references relied upon by the Examiner to arrive at the claimed invention; and (3) the prior art must provide one of ordinary skill with a reasonable expectation of success.

Here, neither prior art reference provides one of ordinary skill with a suggestion or motivation to modify or combine the teachings of the references. Nowhere in Kolehmainen is there a suggestion to provide alignment structures to ensure a proper alignment between the lid and the wells in the tape. Also, the nature of the sample transport device does not require alignment, as the placement of the sample is automated (see figure 1).

Hafeman also does not provide motivation to combine the references. That is, there is no teaching or suggestion in Hafeman to combine the alignment structures with a hybridization

chamber as set forth in the claims. Accordingly, Applicants submit there is no motivation to combine the references.

In addition, Applicants note that the references alone, or in combination do not teach all elements of the present invention, which is a requirement for a finding of obviousness under 35 USC section 103. Neither reference teaches a chamber comprising a base plate with cavity formed in the base plate for holding an array component (claims 15 and 16), or a chamber with a base plate comprising a cavity and a first array component in the cavity (claims 32 and 33). Accordingly, each element of the claims is not taught in the references either alone or in combination.

Accordingly, Applicants submit that there is no motivation to combine the references. In addition, Applicants submit that not all of the claim elements are taught in the cited references. Accordingly, Applicants submit that a *prima facie* case of obviousness has not been established. Applicants request that the rejection be withdrawn.

Claim Rejections under 35 U.S.C. § 103 Kolehmainen *et al.* in view of Kearns *et al.*

The Examiner rejects claims 18 and 34 under 35 U.S.C. § 103 as being unpatentable over Kolehmainen *et al.* in view of Kearns *et al.* Specifically, the Examiner states that although Kolehmainen *et al.* does not teach a device including a fluid handling means, Kearns discloses that it is known in the art to provide a microtiter plate array with an array of detectors for each well wherein the structure includes a manifold for contacting the well contents with a fluid. Applicants respectfully traverse.

The Kolehmainen *et al.* reference has been discussed above.

Kearns *et al.* teaches a radiometric analysis system for solid support samples. More particularly, Kearns teaches a system using an array of radiation counters for measuring the radioactivity of a corresponding array of radioactive samples deposited on a solid support. The manifold to which the Examiner refers is a pressurized gas manifold plate (col.4, lines 50-51 and col. 4, lines 53-55).

In contrast claims 18 provides a hybridization chamber for holding a first array component, a lid comprising at least one component port for immobilizing a second array component, and a sealant, wherein the chamber is connected to at least one fluid handling device. Claim 34 provides a hybridization chamber that includes a first array component in a cavity of a base plate, a lid comprising at least one component port and a second array component in the port, and a sealant, wherein the chamber is connected to at least one fluid handling device.

As the Examiner is aware, when rejecting claims under 35 U.S.C. §103, to establish a *prima facie* case, three basic criteria must be met: (1) the prior art, either alone or in combination, must teach or suggest every limitation of the rejected claims; (2) the prior art must provide one of ordinary skill with a suggestion or motivation to modify or combine the teachings of the references relied upon by the Examiner to arrive at the claimed invention; and (3) the prior art must provide one of ordinary skill with a reasonable expectation of success.

In this regard, Applicants submit neither prior art reference either alone or even when combined provides the requisite motivation for the combination of the references. That is, Kolehmainen does not teach or suggest any combination with a reference that teaches a fluid handling device. Moreover, Kearns fails to provide any motivation for combination with a reference directed to a hybridization chamber comprising a base plate with a cavity for holding arrays. More specifically, one of ordinary skill in the art would not be motivated to combine a

pressurized gas manifold of a radiometric analysis system with a Hybridization chamber for holding arrays. Accordingly, Applicants submit that the references fail to provide teachings that would motivate one of skill of the art to combine the references.

In addition, the prior art references alone or in combination fail to teach every limitation of the rejected claims. Neither reference teaches a fluid handling device. That is, the manifold disclosed by Kearns is a pressurized gas manifold, not a fluid handling device. Nor do the references teach a chamber comprising a base plate with a cavity for holding an array component. Accordingly, not all claim elements are taught in the cited references.

Accordingly, Applicants submit that there is no motivation to combine the references. In addition, Applicants submit that not all of the claim elements are taught in the cited references. Accordingly, Applicants submit that a *prima facie* case of obviousness has not been established. Applicants request that the rejection be withdrawn.

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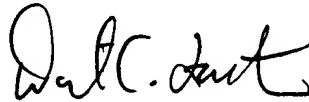
CONCLUSION

Applicants respectfully request that the rejections be withdrawn, and submit that the application is now in condition for allowance; early notification of such is solicited. If, upon review, the Examiner feels there are additional outstanding issues, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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Marked Up Version

Specification

This application [is a continuing application of] claims the benefit of U.S.S.N.s 60/113,968, filed December 28, 1998[,]. The instant application is a Continuation In Part of 09/256,943, filed February 24, 1999, and of 09/473,904, filed December 28, 1999, and PCT/US99/31022, filed December 28, 1999, all of which are incorporated by reference in their entirety.

Claims

15. (Amended) The chamber according to claim 13 further comprising at least one alignment feature, wherein said at least one alignment feature facilitates alignment of said lid with said base plate.

16. (Amended) The chamber according to claim [15] 13 further comprising at least one alignment feature, wherein said at least one alignment feature is a male and female fitting.

17. (Amended) The chamber according to claim 13, [further] wherein said first array component is a microtiter plate.

18. (Amended) The chamber according to claim 13 [further comprising], wherein said chamber is connected to at least one fluid handling device.

30. (Amended) The chamber according to claim 29, wherein [Wherein] said first array component is a microtiter plate.

31. (Amended) The chamber according to claim 29, wherein [Wherein] said second array component is a fiber optic bunch.

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32. (Amended) The chamber according to claim 29 further comprising at least one alignment feature, wherein said at least one alignment feature facilitates alignment of said lid with said base plate.

34. (Amended) The chamber according to claim 29 [further comprising], wherein said chamber is connected to at least one fluid handling device.